Message

From: Pierce, Amanda [pierce.amanda@epa.gov]

Sent: 4/17/2020 12:35:19 PM

To: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: RE: request related to section G for 93167-EUP-E

Perfect!

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: Friday, April 17, 2020 7:30 AM

To: Pierce, Amanda <pierce.amanda@epa.gov>

Subject: RE: request related to section G for 93167-EUP-E

Ex. 5 Deliberative Process (DP)

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Pierce, Amanda <pierce.amanda@epa.gov>

Sent: Thursday, April 16, 2020 1:03 PM

To: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov >

Subject: RE: request related to section G for 93167-EUP-E

Oh actually I see that the sentence I drafted has been a bit tweaked. This sentence was sent to them:

Ex. 5 Deliberative Process (DP)

From: Pierce, Amanda

Sent: Thursday, April 16, 2020 12:55 PM

To: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>; Striegel, Wiebke < Striegel. Wiebke@epa.gov>

Subject: RE: request related to section G for 93167-EUP-E

Hey Eric,

That's great that they do indeed plan to do what we assumed. If Nathan could also just cite to those sections that he mentioned in the sentence that says they will perform penetrance monitoring, I think that would close the loop for us.

Amanda

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: Thursday, April 16, 2020 12:39 PM

To: Pierce, Amanda ceamanda@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>

Subject: FW: request related to section G for 93167-EUP-E

Thoughts on this response?

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

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Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Nathan Rose < nathan.rose@oxitec.com>

Sent: Thursday, April 16, 2020 11:10 AM

To: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>; Matthews, Keith < KMatthews@wiley.law>

Cc: Mendelsohn, Mike < Mendelsohn. Mike@epa.gov >; Reynolds, Alan < Reynolds. Alan@epa.gov >; Kevin Gorman

< Kevin. Gorman@oxitec.com >

Subject: RE: request related to section G for 93167-EUP-E

Hi Eric

This understanding is correct.

- Fluorescence will be used as the screening method (5.2.6.1 and 5.9.4.1), screening larvae hatched from ovitraps (more detail on hatching methods in 5.3.3 and 5.11.2) in the trial areas.
- The sample size (number of ovitraps) and frequency of ovitrap monitoring is described for Trial A in Section 5.2.6.2 and for Trial B in Section 5.9.4.2.

When we resubmit section G, I will add a sentence to Section 5.9.4.1 to clarify this for Trial B, but will wait until Monday in case you have additional requests.

Kind regards Nathan

From: Bohnenblust, Eric < Bohnenblust. Eric@epa.gov>

Sent: 16 April 2020 15:55

To: Matthews, Keith <KMatthews@wiley.law>; Nathan Rose <nathan.rose@oxitec.com>

Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>

Subject: request related to section G for 93167-EUP-E

Keith and Nathan,

We have a request for some clarification related how Oxitec is assessing penetrance, which I think will be most easily addressed in the section G for the experimental program.

In Section 5.2.6.1, it is stated that fluorescence will be used to screen for penetrance. In the mortality assessment sections (5.3.3, 5.11.2) Oxitec provides the protocol for how penetrance can be assessed and in the eggs sections (5.2.6.2, 5.9.4.2) Oxitec provides information on the sample size/frequency in which penetrance can be assessed. Can you confirm that the methods referenced in Sections 5.2.6.1/5.9.4.1 (The eggs and mortality assessment sections) are the methods/frequency that will be used for penetrance monitoring. If these are not the methods/frequency used for penetrance monitoring could you provide additional detail on the methods/frequency that will be used for penetrance

monitoring. In addition please also make sure that the corresponding section for Trial B (5.9.4.1) also references the penetrance monitoring appropriately.

If you want to initially respond via email today or tomorrow to confirm or provide the details that is fine, then Monday at 10:30 we can touch base about submission of a revised section G in case we have any additional requests.

Thanks.

Eric Bohnenblust, Ph.D Senior Biologist Emerging Technologies Branch (ETB) Biopesticides and Pollution Prevention Division (BPPD)

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